A No.
Q You would only include data that made your point?
A I would include in the declaration representative of reliable and conclusive data.
Q If the data were equivocal would you include it?
A Not -- I think you have to provide representative data.
Q Is that what Dr. Atkinson told you?
A No.
Q That was your own decision?
A Yes, I wrote the declaration. It was my decision what information went into the declaration.
Q You wrote the declaration?
A I did.
Q Did you write all the drafts of it?
A Yes, I wrote all the drafts of it in the sense that it's my declaration and I did all the judgments and provided all the technical information. You have to bear in mind this was the first declaration I was ever involved in. Obviously there's a legal component associated with the declaration. I needed guidance in providing the legal framework associated with it. I couldn't draft that entirely on my own.
Q You did read it before you signed it; is that correct?
A Yes.
Q And you affirmed that it was your affidavit?
A Oh, yeah.

MR. RUBIN: I have no more questions.

MR. LEWIN: No redirect, Your Honor.

THE COURT: Dr. Hempenstall, when did you learn that you were being charged with misconduct in this case? Do you recall when you first became conscious of that.

THE WITNESS: Sometime after February, after my deposition.

THE COURT: Part of what is being urged on the Court in this case is an argument that basically says this: The UK ingredients were essentially the same as the U.S. ingredients. On what rational basis would one acting in good faith exclude test results that were equivocal or unfavorable on the same ingredients?

THE WITNESS: I think if the data makes you believe there is something odd about the results, then that is reason to do so, to set them aside, and that's the judgment that I made.

THE COURT: A possible response to that is under that approach if you have a set of data 50 percent of which is what you might call bad because it's not consistent with the hypothesis, and 50 percent of it is consistent with the hypothesis, under your approach, arguably, you exclude the bad 50 percent and submit the other 50 percent and represent it as the data. Do you see how that argument can be formulated?

THE WITNESS: I can see your point. As I said, I looked at the data as a whole, I saw inconsistencies and problems in terms of the SP88/026 and I could have included the data at 20 degrees, but if I had taken that out and used it like that I would be accused of taking it out of context. It's easier to say there is something wrong here, let's put it to one side and look at the rest of the data. We have three other programs and they all clearly show an enhancing effect.

THE COURT: Has 20-degree data ever been used, in your experience?

THE WITNESS: It depends what you are trying to do.

THE COURT: On the formulation?

THE WITNESS: On this formulation I don't know. It all depends what you are trying to do. As I was pointing out before, if the conditions of the tests don't allow enough change in something to occur, whether 20 or 50 or whatever, you can't look for differences.

THE COURT: You are suggesting that there may be, and I suppose there are formulations for which the absence of change that you have described at 20 degrees when it comes to ranitidine would be true at 50 or perhaps -- well, I don't suppose true at 50, but at other temperature points, and you would exclude the data.

THE WITNESS: Well, no, I'm not saying that. I'm

saying if you are looking, if you are setting up a study to look for a difference between two things, then that study must bring about a certain amount of change.

THE COURT: Right.

THE WITNESS: For ranitidine for Zantac Syrup, or formulation at 20 degrees, there isn't enough change.

THE COURT: What I'm trying to get at --

THE WITNESS: There might be enough change at 20 degrees in another product.

THE COURT: I'm trying to ask you in your experience can you give us any other examples of a temperature point where the change was so di minimis, so unmeasurable or so insignificant that you would disregard data at that temperature point?

THE WITNESS: If you are looking for differences, then there are.

THE COURT: Give us an example.

THE WITNESS: Ranitidine syrup.

THE COURT: Move away from ranitidine.

THE WITNESS: If you have a stable product which in formulation one is very stable, doesn't change, if you add another set of ingredients to it, it's so chemically stable, if you put those both on test at 20 or at 50 you may find there is no difference after a period of time. Although the different ingredients may want to interact with the active

ingredient in a different way. Because there is no change occurring you can't compare them.

THE COURT: Let me try it one more time. Can you give us in your experience a specific formulation where you have encountered the same oddity, namely where you have sought to measure changes in stability but that the degradation rate at a particular temperature point was so small that you discounted or excluded data included at that temperature rate?

THE WITNESS: This is the only occasion where it was compared formally in this way.

THE COURT: You have no comparable experience?

THE WITNESS: No, I can't provide it.

THE COURT: You can see why then the hypothesis that it was okay to exclude the 20-degree data is untestable. If you can't give us an example of where it might have occurred in some other instance, then Dr. Carstensen is sort of left to say this is insupportable and no scientist would do this. Which is essentially what he said here.

THE WITNESS: That is why you carry out the test under accelerated conditions, to bring about this change. It gives you a more reliable set of figures to analyze.

THE COURT: Okay. The problem is that defendants here are arguing that you took a heads I win, tails you lose approach to your data. That you conveniently, according to

the defendants, have formulated, to coin a phrase, a rationale for getting rid of that which doesn't work, albeit in the course of getting rid of that which doesn't work, i.e., some of the UK data, you also got rid of some of the good UK data. You threw it all out, you didn't need it in your approach because you had this U.S. data. But what the defendants are arguing is that it was data based on the same formulation.

THE WITNESS: Yes.

THE COURT: And so how is it any different than if you had simply run a few more batches on the U.S. ingredients and come up with the same bad data you wouldn't have excluded that, presumably? So part of the question is how can you slice the melon quite where you sliced it? You have one melon and you say I'm going to eat the good part of this melon, but you don't know which is the good part until you cut it open. You cut it open, look at it and see which is the good part and which is the bad part. You discard the bad part and say I had a wonderful melon.

THE WITNESS: As I say, I don't think that the 20-degree data is appropriate. It's unreliable because of the errors in things like analysis. You actually get a wrong result that way.

THE COURT: The problem is you don't have any other --

THE WITNESS: I have no similar example to give I'm afraid.

THE COURT: That makes your job more difficult and my job perhaps more difficult. What about the half melon analogy, does that make sense?

THE WITNESS: I take your point.

THE COURT: You take a crayon and on one half of the melon you write UK and the other half you write U.S. and you discard the UK half and represent to the Patent Office, this is their argument, that you had a great melon here, and this is a melon that nobody anticipated but in fact rotten melons come all the time.

THE WITNESS: If you look at all the data it's overwhelming that there is an effect of ethanol. I explained how I went through all the process. There are four studies here. The UK, there is some good data in the UK, the U.S., the Zantac Syrup with different concentrations and the ranitidine solution. Three are very supportive. The UK it's difficult.

THE COURT: Okay.

THE WITNESS: I believe what I did was appropriate. If I was asked to do this again I would do it the same way.

THE COURT: Not to prolong this, any further questions?

MR. RUBIN: No, Your Honor.